## **REMARKS**

Early and favorable reconsideration of this application is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1-22 are pending in the instant application. In the Office Action mailed July 27, 2004 (the "Office Action"), the Examiner has rejected Claims 1, 3-7, 9-13, 15, 17, 19, 20 and 22 under 35 U.S.C. 101 for double patenting in view of U.S. Patent No. 5,716,376 to Roby et al.; rejected Claims 1, 3-7, 9-13, 15, 17, 19, 20 and 22 under 35 U.S.C. 102(b) as anticipated by Roby et al.; and rejected Claims 1-22 under 35 U.S.C. §103 as obvious over Roby et al. in view of U.S. Patent No. 6,267,782 to Ogle et al. and U.S. Patent No. 6,183,499 to Fischer et al.

According to the Examiner, Claims 1, 3-7, 9-13, 15, 17, 19, 20 and 22 of the present application claim the same invention as Claims 1, 2, 4, 5, 7, 8, 15, 16 and 17 of Roby et al. This rejection is respectfully traversed, as the subject matter claimed in the present application is different from the subject matter claimed by Roby et al.

Claim 1 of Roby et al. reads as follows:

- 1. A surgical suture coating comprising:
- a) a copolymer comprising a predominant amount of epsilon-caprolactone and a minor amount of at least one other copolymerizable monomer: and
- b) a salt of a lactylate ester of a C<sub>10</sub> or greater fatty acid selected from the group consisting of magnesium stearoyl lactylate, aluminum stearoyl lactylate, barium stearoyl lactylate, zinc stearoyl lactylate, calcium palmityl lactylate, magnesium palmityl lactylate, aluminum palmityl lactylate, barium palmityl lactylate, or zinc palmityl lactylate, calcium olelyl lactylate, magnesium olelyl lactylate, aluminum olelyl lactylate, barium olelyl lactylate, and zinc olelyl lactylate.

All of the other independent claims of Roby et al. recite these same salts of lactylate esters, i.e., calcium stearoyl lactylate (claim 3), or magnesium stearoyl lactylate, aluminum stearoyl lactylate, barium stearoyl lactylate, zinc stearoyl lactylate, calcium palmityl lactylate, magnesium palmityl lactylate, aluminum palmityl lactylate, barium palmityl lactylate, or zinc palmityl lactylate, calcium olelyl lactylate, magnesium olelyl lactylate, aluminum olelyl lactylate, barium olelyl lactylate, zinc olelyl lactylate and calcium stearoyl lactylate (claims 13, 15 and 16).

The present application does not recite the same composition as the claims of Roby et al., but rather recites different lactylate salts. For example, claim 1 of the instant application reads as follows:

- 1. A surgical suture coating comprising:
- a) a copolymer comprising a predominant amount of epsilon-caprolactone and a minor amount of at least one other copolymerizable monomer; and
- b) an effective antimicrobial amount of a fatty acid ester salt selected from the group consisting of lithium stearoyl lactylate, potassium stearoyl lactylate, rubidium stearoyl lactylate, cesium stearoyl lactylate, francium stearoyl lactylate, sodium palmityl lactylate, lithium palmityl lactylate, potassium palmityl lactylate, rubidium palmityl lactylate, cesium palmityl lactylate, francium palmityl lactylate, sodium olelyl lactylate, lithium olelyl lactylate, potassium olelyl lactylate, rubidium olelyl lactylate, cesium olelyl lactylate, and francium olelyl lactylate.

Independent claims (claims 13, and 17) of the present application recite the same list of salts. Claims 4, 15, and 20 specifically recite sodium stearoyl lactylate.

Because Roby et al., claim different lactylate salts from those claimed herein, it is respectfully submitted that the claimed subject matter of the instant application is <u>not</u> the same

invention as claimed in Roby et al., and withdrawal of the rejection of Claims 1, 3-7, 9-13, 15, 17, 19, 20 and 22 under 35 U.S.C. 101 is respectfully requested.

The Examiner has next rejected Claims 1, 3-7, 9-13, 15, 17, 19, 20 and 22 as anticipated by Roby et al. This rejection is traversed. Roby et al. does not teach or suggest the presently claimed compositions. Rather, in Roby et al. metals other than those claimed herein are utilized to form a fatty acid ester salt. Roby et al. simply fails to disclose the specifically recited salts. Accordingly, as Roby et al. utilizes different metals to form its salts compared with those presently claimed, Roby et al. does not anticipate the salts of the present application and withdrawal of this rejection is respectfully requested.

The rejection of Claims 1-22 as obvious under 35 U.S.C. 103 over Roby et al. in view of Ogle et al. and Fischer et al. is similarly traversed. As noted above, nowhere does Roby et al. disclose or suggest a suture coating comprising an epsilon-caprolactone copolymer with a minor amount of at least one other copolymerizable monomer having "an effective antimicrobial amount of a fatty acid ester salt selected from the group consisting of lithium stearoyl lactylate, potassium stearoyl lactylate, rubidium stearoyl lactylate, cesium stearoyl lactylate, francium stearoyl lactylate, sodium palmityl lactylate, lithium palmityl lactylate, potassium palmityl lactylate, rubidium palmityl lactylate, francium palmityl lactylate, sodium olelyl lactylate, cesium palmityl lactylate, rubidium olelyl lactylate, sodium olelyl lactylate, and francium olelyl lactylate, as presently recited in claim 1. Rather, Roby et al. discloses salts of lactylate esters of a C<sub>10</sub> or greater fatty acid utilizing an

alkaline earth metal or transition metal (i.e., calcium, magnesium, aluminum, barium, or zinc) in forming the salt.

Ogle et al. fails to remedy the deficiencies of Roby et al. Ogle et al. is directed to medical methods for adhering antimicrobial metals, such as elemental silver, to medical articles.

Nowhere in Ogle et al. is there any mention of utilizing an effective antimicrobial amount of a fatty acid ester salt derived from an alkali metal in combination with an epsilon-caprolactone copolymer as a suture coating as presently claimed by applicants. Thus, neither Ogle et al. nor Roby et al., taken alone or in any combination, render claims 1-22 obvious.

Fischer et al. similarly fails to remedy the deficiencies of Roby et al. Fischer et al. is directed to surgical filaments which may have a biocompatible polymeric coating. Where the coating is bioabsorbable, it may also contain medicaments such as antibiotics or silver compounds. Nowhere in Fischer et al. of a is there any mention of utilizing an effective antimicrobial amount of a fatty acid ester salt derived from an alkali metal in combination with an epsilon-caprolactone copolymer as a suture coating as presently claimed by applicants.

Accordingly, neither Roby et al., Ogle et al. nor Fischer et al., taken alone or in any combination, render the claims of the instant application obvious.

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It is believed that all the claims of the application as presented, i.e., Claims 1-22, are in condition for allowance. If there is any point requiring discussion prior to allowance, the Examiner is earnestly solicited to telephone the undersigned attorney for Applicants at the address below.

Respectfully submitted,

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